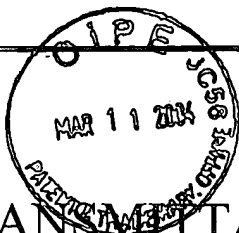


*image*

**TRANSMITTAL  
FORM**



Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Hartmann
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MERCK-2056
Patent No.	Not applicable
Issue Date	Not applicable

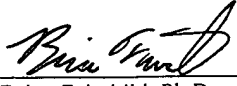
**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____] <input type="checkbox"/> Petition for Extension of Time <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (A82-A96 and C191-C244) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application <input type="checkbox"/> Formal Drawing(s) <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program <input type="checkbox"/> Amendment After Allowance <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate) <input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mail <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8 <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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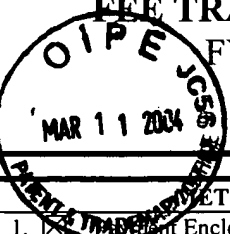
**CORRESPONDENCE ADDRESS**

Direct all correspondence to: Patent Administrator  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
 Tel. No.: (617) 248-7000  
 Fax No.: (617) 248-7100

**SIGNATURE BLOCK**

Respectfully submitted,  
  
 Brian Fairchild, Ph.D.  
 Attorney for Applicants  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110

Date: March 9, 2004  
 Reg. No. 48,645  
 Tel. No.: (617) 248-7697  
 Fax No.: (617) 248-7100

<b>FREE TRANSMITTAL</b> FY 2004 		<i>Complete if Known</i>	
		Application Serial Number	09/708,506
		Filing Date	November 9, 2000
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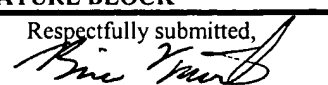
  

<b>METHOD OF PAYMENT</b> 1. <input checked="" type="checkbox"/> Check <input type="checkbox"/> Money Order <input type="checkbox"/> Other 2. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531. <input type="checkbox"/> Required Fees (copy of this sheet enclosed). <input checked="" type="checkbox"/> Additional fee required under 37 CFR 1.16 and 1.17. <input checked="" type="checkbox"/> Overpayment Credit. 3. <input type="checkbox"/> Applicant claims small entity status.	<b>FEE CALCULATION (continued)</b> <b>3. ADDITIONAL FEES</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee (\$)</th> <th>Small Entity Fee (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr><td>130</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr> <tr><td>50</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td></td></tr> <tr><td>130</td><td>130</td><td>Non-English specification</td><td></td></tr> <tr><td>2,520</td><td>2,520</td><td>Request for ex parte reexamination</td><td></td></tr> <tr><td>110</td><td>55</td><td>Extension for reply within first month</td><td></td></tr> <tr><td>420</td><td>210</td><td>Extension for reply within second month</td><td></td></tr> <tr><td>950</td><td>475</td><td>Extension for reply within third month</td><td></td></tr> <tr><td>1480</td><td>740</td><td>Extension for reply within fourth month</td><td></td></tr> <tr><td>2010</td><td>1005</td><td>Extension for reply within fifth month</td><td></td></tr> <tr><td>330</td><td>165</td><td>Notice of Appeal</td><td></td></tr> <tr><td>330</td><td>165</td><td>Filing a brief in support of an appeal</td><td></td></tr> <tr><td>290</td><td>145</td><td>Request for oral hearing</td><td></td></tr> <tr><td>130</td><td>130</td><td>Petitions to the Commissioner</td><td></td></tr> <tr><td>180</td><td>180</td><td>Submission of Information Disclosure Statement</td><td>180.00</td></tr> <tr><td>770</td><td>385</td><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td></td></tr> <tr><td>770</td><td>385</td><td>For each additional invention to be examined (37 CFR 1.129(b))</td><td></td></tr> <tr><td>100</td><td>100</td><td>Certificate of Correction for applicant's error</td><td></td></tr> <tr><td>110</td><td>55</td><td>Submission of Terminal Disclaimer</td><td></td></tr> <tr><td colspan="2">Other fee (Specify)</td><td></td><td></td></tr> <tr><td colspan="2">Other fee (Specify)</td><td></td><td></td></tr> </tbody> </table>	Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid	130	65	Surcharge - late filing fee or oath		50	25	Surcharge - late provisional filing fee or cover sheet		130	130	Non-English specification		2,520	2,520	Request for ex parte reexamination		110	55	Extension for reply within first month		420	210	Extension for reply within second month		950	475	Extension for reply within third month		1480	740	Extension for reply within fourth month		2010	1005	Extension for reply within fifth month		330	165	Notice of Appeal		330	165	Filing a brief in support of an appeal		290	145	Request for oral hearing		130	130	Petitions to the Commissioner		180	180	Submission of Information Disclosure Statement	180.00	770	385	Filing a submission after final rejection (37 CFR 1.129(a))		770	385	For each additional invention to be examined (37 CFR 1.129(b))		100	100	Certificate of Correction for applicant's error		110	55	Submission of Terminal Disclaimer		Other fee (Specify)				Other fee (Specify)			
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<b>CORRESPONDENCE ADDRESS</b> Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibault, LLP High Street Tower-125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100	<b>SIGNATURE BLOCK</b> Respectfully submitted,  Brian Fairchild, Ph.D. Attorney for the Applicants Testa, Hurwitz & Thibault, LLP High Street Tower-125 High Street Boston, MA 02110 Date: March 9, 2004 Reg. No.: 48,645 Tel. No.: (617) 248-7697 Fax No.: (617) 248-7100
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PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.*  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: ERYTHROPOIETIN FORMS WITH IMPROVED PROPERTIES

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 9, 2004.

  
Malecia Allen

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 page);
2. Fee Transmittal Form (1 page);
3. Supplemental Information Disclosure Statement (2 pages);
4. Form PTO-1449 (5 pages);
5. Copies of cited references A82-A96 and C191-C244;
6. A check in the amount of \$180.00; and
7. A return receipt postcard.



PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.* CONF. NO.: 2626  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: Erythropoietin Forms with Improved Properties

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

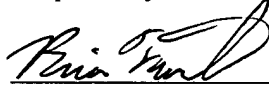
Applicants believe no additional fee is due for consideration of this submission. Nevertheless, if such a fee is required, please debit account 20-0531.

Date: March 9, 2004  
Reg. No. 48,645

Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100

3034886-1

Respectfully submitted,



\_\_\_\_\_  
Brian Fairchild, Ph.D.  
Attorney for Applicants  
Testa, Hurwitz, & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110

FORM PTO - 1449

ATTORNEY DOCKET NO.: MERCK-2056

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

APPLICANTS: Hartmann et al.

SERIAL NO.: 09/708,506 CONF. NO.: 2626

FILING DATE: November 9, 2000 GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A82	4,703,008	10/27/87	Lin			
	A83	5,457,038	10/10/95	Trinchieri et al.			
	A84	5,547,933	8/20/96	Lin			
	A85	5,618,698	4/8/97	Lin			
	A86	5,756,349	5/26/98	Lin			
	A87	5,955,422	9/21/99	Lin			
	A88	6,231,536	5/15/01	Lentz			
	A89	6,284,536	9/4/01	Morrison et al.			
	A90	6,340,742	1/22/02	Burg et al.			
	A91	6,506,405	1/14/03	Desai et al.			
	A92	6,583,272	6/24/03	Bailon			
	A93	6,586,398	7/1/03	Kinstler et al.			
	A94	2002/0142374	10/3/02	Gallo et al.			
	A95	2003/0003529	1/2/03	Bayer			
	A96	2003/0012789	1/6/03	Blumberg et al.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)						
	C191	Angal et al., (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30(1):105-108.					
	C192	Becker et al., (1996), "Long-lived and Transferable Tumor Immunity in Mice after Targeted Interleukin-2 Therapy," <u>J. Clin. Invest.</u> , 98(12):2801-2804.					
	C193	Becker et al., (1996), "T Cell-mediated Eradication of Murine Metastatic Melanoma Induced by Targeted Interleukin-2 Therapy," <u>J. Exp. Med.</u> , 183(50):2361-2366.					
	C194	Bitonti et al., (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.					
	C195	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships: Mutant Proteins that Test a Model of Tertiary Structure," <u>The Journal of Biological Chemistry</u> , 268(21):15983-15993.					
	C196	Briggs et al., (1974), "Hepatic Clearance of Intact and Desialylated Erythropoietin," <u>American Journal of Physiology</u> , 227(6):1385-1388.					
EXAMINER				DATE CONSIDERED			



FORM PTO - 1449

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MERCK-2056

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	C197	Chuang et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the Anticancer Drug Taxol," <u>Cancer Research</u> , 54:1286-1291.					
	C198	Darling et al., (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.					
	C199	Davis et al., (2003), "Immunocytokines: Amplification of Anti-cancer Immunity," <u>Cancer Immunol. Immunother.</u> , 52:297-308.					
	C200	Dolman et al., (1998), "Suppression of Human Prostate Carcinoma Metastases in Severe Combined Immunodeficient Mice by Interleukin 2 Immunocytokine Therapy," <u>Clin. Cancer Research</u> , 4(10):2551-2557.					
	C201	Duncan et al., (1988), "The Binding Site for C1q on IgG," <u>Nature</u> , 332:738-740.					
	C202	Egrie et al., (2001), "Development and Characterization of Novel Erythropoiesis Stimulating Protein (NESP)," <u>Nephrol. Dial. Transplant.</u> , 16(Supp 3):3-13.					
	C203	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.					
	C204	Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti-GD2 Antibody 14.G2a Plus Interleukin-2 in Children with Refractory Neuroblastoma," <u>Cancer</u> , 80(2):317-333.					
	C205	Gan et al., (1999), "Specific Enzyme-linked Immunosorbent Assays for Quantitation of Antibody-cytokine Fusion Proteins," <u>Clinical and Diagnostic Laboratory Immunology</u> , 6(2):236-42.					
	C206	Gillies et al., (1991), "Expression of Genetically Engineered Immunoconjugates of Lymphotoxin and a Chimeric Anti-ganglioside GD2 Antibody," <u>Hybridoma</u> , 10(3):347-56.					
	C207	Gillies et al., (2002), "Bi-functional Cytokine Fusion Proteins for Gene Therapy and Antibody-targeted Treatment of Cancer," <u>Cancer Immunol. Immunother.</u> , 51(8):449-60.					
	C208	Gillies et al., (2002), "Improved Circulating Half-life and Efficacy of an Antibody-interleukin 2 Immunocytokine Based on Reduced Intracellular Proteolysis," <u>Clin. Cancer Research</u> , 8(1):210-216.					
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<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>				<b>ATTORNEY DOCKET NO.: MERCK-2056</b> <b>APPLICANTS: Hartmann et al.</b> <b>SERIAL NO.: 09/708,506      CONF. NO.: 2626</b> <b>FILING DATE: November 9, 2000      GROUP: 1647</b>			
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SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MERCK-2056

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